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25944	7590	11/14/2008	EXAMINER	
OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850			HOBBS, LISA JOE	
ART UNIT	PAPER NUMBER			
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,989	<b>Applicant(s)</b> MERCADER BADIA ET AL.
	<b>Examiner</b> Lisa J. Hobbs	<b>Art Unit</b> 1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on **18 July 2008**.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) **1-11** is/are pending in the application.  
 4a) Of the above claim(s) **6-10** is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) **1-5 and 11** is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/0256/06)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Status***

Claims 1-11 are active in the case. Claims 1-5 and 11 are under examination; claims 6-10 are withdrawn as drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holbrook (EP 0 295 116), Taylor et al. (WO 2000/63668) and Grant et al. (US 5624815). Holbrook teaches apparatus and methods for microorganism culture and testing comprising liquid medium in a Stomacher device (page 9 line 11), with one or more tube carriers dipping into the liquid media, but projecting above the liquid media surface (claim 1), where the carrier tubes are loaded with appropriate media and in contact with the medium in the culture vessel (page 9 lines 19-22), at a temperature of 37 °C to 41.5 °C (page 9, line 23). Holbrook allows the bacteria to move from the liquid media being tested into the supported media during the testing period (claim 1). Holbrook also contemplates at least two supported media in series (claim 3).

Taylor et al. disclose apparatus and methods developed to automatically deliver samples to reaction vessels, analytical devices or any location where sample introduction is desired (page 2, lines 8-12). They use channels, e.g., capillaries, with temperature control devices in communication with the channels allowing the heating/cooling of the capillaries to control the movement of the reagents via pressure changes (page 2). As well, they contemplate the use of one or more temperature control devices to heat and/or cool the entire capillary or discrete locations (page 3, lines 8-12). In paragraph three on pages three, Taylor et al. disclose the theory behind the use of temperature controls and temperature changes. They reveal that "an aliquot of sample is drawn into the capillary to fill the volumetric void left by the contracting gas when the system is cooled" (page 3, line 22). They particularly disclose a preferred embodiment wherein

a sample delivery system is used to introduce a sample into a sample analysis apparatus (page 3, lines 29-31).

Grant et al. teach a “method for analyzing solid material in a liquid sample, which comprises the steps of: substantially uniformly distributing the sample by passage through a plurality of discrete wells provided in an integral member and whose bases are defined by filter material that retains the solid material and allows the passage of liquid, the concentration of solid material being such that it is absent in at least one well; and analyzing the wells for the presence of retained solid material” (claim 1). As well as a “device adapted for use in a method for analyzing solid material in a liquid sample comprises the combination of: a container for the sample; a unit comprising a number of discrete wells adapted to retain the solid material and allow the passage of liquid under the application of reduced pressure; structure for drawing liquid from the container and through the wells under reduced pressure; and a manifold or other element that provides uniform distribution of the sample passing from the container into the wells” (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Holbrook, Taylor et al. and Grant et al. to achieve the invention as described. Separation of a sample for the purposes of analyzing a suspected microbacterial component is described by both Holbrook and Grant et al. While Holbrook teaches allowing the bacteria to move into the test system under their own motile power, Grant et al. teach using reduced pressure created by suction and Taylor et al. teach using heating and cooling to create the pressure gradients necessary to move liquid samples among test containers. Each of these references teaches that the sample containers must be open to each other, to allow

movement of the samples to be tested, and each teaches a variety of temperatures for the assays, as well as Taylor et al. teaching the use of heating and cooling temperatures to control the pressure of the containers and the movement of the sample fluids. One would be motivated to do sample testing assays and have a reasonable expectation of success because of the importance to the health care community and pharmaceutical industry of selective testing for bacteria and the specificity of the teachings of the cited references, among many others, disclosing the mechanics of selective bacterial assays.

*Response to Arguments*

Applicant's arguments filed 18 July 2008 have been fully considered but they are not persuasive. Applicants argue that each reference does not teach the recited elements, e.g., Holbrook and Grant do not teach temperature changes and Taylor does not teach temperature changes that move liquids comprising microbiological samples. However, when taken as a whole the references do teach the invention as claimed. Holbrook teaches that one of skill in the art would know and be motivated to move culture liquid between sample areas, including two separate media in series. Grant teaches methods of detection and or identification of bacteria using devices can be created and adapted to move the culture liquid between compartments. Taylor et al. teach that it is known to those in the art that temperature changes can be used to move biological samples within a device to detect and/or identify bacteria, specifically they teach methods of movement of samples for "diagnostic applications (e.g. to identify blood components), applications to detect toxins (e.g. bacteria)" (p. 6).

Applicants argue that Taylor et al.'s teachings are "unrelated to the field of microbiology and the use of culture medium to grow a living organism". Applicants also argue that one of

ordinary skill would not purposely induce fluctuations in a culture's incubation temperature, also that Taylor et al. prefer to analyze a gas. However, the claims do not recite such limitations on the application or on the movement of liquid in this method; the claim recites "a method for detecting and/or identifying bacteria present in a liquid or solid sample", elements of which are taught by Taylor et al., as shown above, and they state that "the concepts taught by this specification apply equally to the use of any volume controller, channel and/or expandable fluid" (p. 6).

Applicants argue that the temperature and volume disclosed in the prior art do not match that of the claims, however the range cited by applicants as viable culture temperature levels (from Holbrook) does match the temperatures claimed by applicants and could be used in a method as suggested by Taylor et al. The volume limitation cited by applicants is not present in the claims and while the claims are read in light of the specification, specific limitations cannot be presumed to be claimed if not recited. As well, applicants argue that certain temperatures are required to maintain viability, but viability is not a limitation recited in the instant claims.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/  
Primary Examiner  
Art Unit 1657

ljh